

Support for the amendments and new claims is found throughout the specification, *e.g.*, at page 8 lines 17-25, page 10 line 24 – page 11 line 2, and page 45 lines 2-24, the sequence listing, the figures, and in the original claims. No new matter enters by these amendments and new claims.

Election/Restrictions

The Examiner has acknowledged Applicants' election, with traverse, of Group IV, Claims 1 and 10-12. The Examiner has maintained that the restriction is proper and has deemed it final. Applicants acknowledge the finality of the restriction requirement but maintain their traversal.

Information Disclosure Statement

Applicants acknowledge the Examiner's indication that she has attached initialed and dated copies of the Applicant's IDS Forms 1449 to the Office Action. Six references were cited in the IDS numbered paper number 11 which the Examiner crossed out. Enclosed with this response is a new IDS and 1449 containing the references that were crossed out by the Examiner.

Applicants respectfully request that the enclosed references be expressly considered during the prosecution of this application, and that they be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

I. Rejection under 35 U.S.C. §112, 1st Paragraph: Written Description

Claims 1 and 10 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Office Action at page 2. Applicants respectfully disagree.

The Examiner acknowledges that the Applicants describe “a DNA sequence of SEQ ID NO: 38 encoding a tocopherol cyclase from *Synechocystis*.” Office Action at page 3. However, the Examiner asserts that Applicants do “not describe any other tocopherol cyclase encoding sequence from *Synechocystis* other than SEQ ID NO: 38 or any other prokaryotic DNA sequences encoding tocopherol cyclases.” Office Action at page 3.

Applicants thank the Examiner for the acknowledgement that the specification discloses a DNA sequence of SEQ ID NO: 38 encoding a tocopherol cyclase from *Synechocystis*, but respectfully disagree with the Examiner’s conclusion.

An adequate written description of a genus of nucleic acids may be achieved by either “a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus.” *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). This Applicants have done.

For example, Applicants have disclosed the nucleic acid sequence of tocopherol cyclase from *Synechocystis* (SEQ ID NO: 38) as well as the nucleic acid sequence of the *Arabidopsis* homologue (SEQ ID NO: 109). See Specification, page 45, lines 23-24 and page 48, lines 6-10.

As such, Applicants have provided a representative number of nucleic acid sequences and have satisfied the *Eli Lilly* test for adequate written description.

Based on the foregoing, it is clear that one of ordinary skill in the art would recognize that Applicants were in possession of the claimed invention. Therefore, it is respectfully submitted that the rejection under 35 U.S.C. § 112, 1st paragraph, written description, is improper and should be withdrawn.

II. Rejection under 35 U.S.C. §112, 1st Paragraph: Enablement

Claims 1-10 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being enabled. The Examiner acknowledges that the isolation and activity of a DNA encoding a tocopherol cyclase from *Synechocystis* of SEQ ID NO: 38 is enabled. However, the Examiner asserts that the Applicants do “not teach any other prokaryotic DNA encoding tocopherol cyclase or any other species with sequence homology to SEQ ID NO: 38... (and)... no guidance is provided regarding the particular domains responsible for particular catalytic activities.” Office Action at page 4. Applicants respectfully disagree.

The present specification discloses how to make and use the claimed invention, including identifying tocopherol cyclase sequences, preparing expression constructs, transforming plants, analyzing transgenic plants, and obtaining tocopherol cyclase sequences. *See, e.g.*, Examples 1-6. The specification discloses many examples of sequences that can be used to transform various host cells. *See* specification, Example 2. Moreover, the specification also discloses examples of cells and plants that have been transformed with the sequences of the present invention. *See, e.g.*, specification, Example 2 and Example 5.

Furthermore, the Examiner has not met the evidentiary burden to impose an enablement rejection. A specification that discloses how to use a claimed invention “must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein.” *In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995), *quoting In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971) (emphasis in original). However, the Examiner has provided neither specific evidence supporting the rejection nor any explanation of why the specification allegedly fails to enable a nucleic acid molecule encoding a tocopherol cyclase, particularly in light of the extensive teaching with Applicant’s specification. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) (“pure conjecture” does not substantiate rejection for lack of enablement).

The Office Action asserts that undue experimentation would be required to make and use the invention as it is claimed. Office Action at page 6. Applicants respectfully disagree. The Examiner relies on Broun *et al.*, Doerks *et al.*, and Smith *et al.*, apparently suggesting that those references teach unpredictability in the art of the present invention. Office Action at pages 4-5. On the basis of Broun *et al.*, Doerks *et al.*, and Smith *et al.*, the Examiner concludes that “[g]iven the lack of guidance for isolating any other tocopherol cyclase genes or elucidating the required sequence domains for particular catalytic activities, the breadth of the claims, the unpredictability in the art in determining protein activity using homology based methods, and the known errors inherent to functional genomics when relying solely on protein prediction programs, undue trial and error experimentation would be needed by one skilled in the art to isolate and evaluate a multitude of non-exemplified prokaryotic tocopherol cyclase genes.” Office Action at page 6.

The Examiner, however, fails to acknowledge the teachings set forth in the specification. As described above in detail, the present specification discloses how to make and use the present invention. More particularly, Applicants have disclosed the nucleic acid sequence of tocopherol cyclase from *Synechocystis* (SEQ ID NO: 38) as well as the nucleic acid sequence of the *Arabidopsis* homologue (SEQ ID NO: 109). See Specification, page 45, lines 23-24 and page 48, lines 6-10.

The specification also discloses how to select genes and how to construct vectors and transform plants. In addition, the specification details methods for confirming increased tocopherol levels. See, e.g., Examples 1, 5 and 6. The Examiner has not indicated how Broun *et al.*, Doerks *et al.*, or Smith *et al.* suggest that such work would be "undue experimentation."

As such, based on the extensive teachings of the specification, the enablement requirement has been met. On the basis of the foregoing, Applicants respectfully request that the Examiner withdraw the enablement rejection under 35 U.S.C. §112, first paragraph.

III. Rejection under 35 U.S.C. §112, 2nd Paragraph: Indefiniteness

Claims 10-12 stand rejected under 35 U.S.C. §112, 2nd paragraph for allegedly failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Specifically, claim 10 stands rejected because the Examiner alleges that there is insufficient antecedent basis for the limitation: "An isolated DNA sequence according to Claim 4, wherein said prokaryotic source" in line 1. Office Action at page 6. Applicants have amended claim 10 to refer to an isolated nucleic acid molecule and to depend from claim 1. Amended claim 10 provides proper antecedent basis. Withdrawal of this rejection is respectfully

requested.

Claims 11 and 12 stand rejected because the Examiner alleges that there is insufficient antecedent basis for the limitation: "wherein said tocopherol cyclase" in line 1. Office Action at page 6. Applicants respectfully disagree. Claims 11 and 12 ultimately depend from claim 1, which includes the recitation "tocopherol cyclase." Therefore, claims 11 and 12 provide proper antecedent basis. Withdrawal of these rejections is respectfully requested.

Conclusion

The presently pending claims are believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. The Examiner is respectfully requested to contact Applicant's undersigned representative at (202) 942-5000 to address any unresolved issues remaining in this application.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe any additional fees are due in conjunction with this filing. However, if any fees under 37 C.F.R. 1.16 or 1.17 are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter Deposit Account No. 50-2387, referencing matter number 16515.054.

Respectfully submitted,

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Marked-Up Claims

1. (Amended) An isolated nucleic acid [sequence] molecule encoding a tocopherol cyclase.
10. (Amended) [An] The isolated [DNA sequence] nucleic acid molecule of claim [4] 1,
wherein said tocopherol cyclase is isolated from a prokaryotic cell source [is a *Synechocystis* sp].
11. (Twice Amended) The [DNA sequence] isolated nucleic acid molecule of claim 10,
wherein said tocopherol cyclase is encoded by a nucleotide sequence of SEQ ID NO: 38.
12. (Twice Amended) The [DNA sequence] isolated nucleic acid molecule of Claim 10,
wherein said [tocopherol cyclase has] nucleic acid molecule encodes an amino acid sequence of
SEQ ID NO: 39.